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Idaho State Board of Pharmacy News

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1199 Shoreline Lane, Suite 303 • Boise, ID 83702

Template Pharmacist Prescribing Protocols Are Available

The Idaho State Board of Pharmacy recently promulgated Rule Docket 27-0104-1701, Rules Governing Pharmacist Prescriptive Authority. This rule docket was unanimously approved by the germane legislative committees and took effect on July 1, 2018.

In furtherance of the prescribing authority set forth in Idaho Code Section 54-1704(5)(e), the rules specifically authorize certain drugs, drug categories, and devices that may be prescribed by an Idaho pharmacist subject to certain requirements.

One specific requirement in Rule 020.03 is that for each drug or drug category the pharmacist intends to prescribe:

> . . . the pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specifies the following:
>
> i. Patient inclusion and exclusion criteria; and
>
> ii. Explicit medical referral criteria.

While the term "protocol" may have different meanings in different settings, the Idaho rules indicate that the patient assessment protocol is to be used to identify patients who may not be appropriate candidates for treatment by the pharmacist and who may need referral to a more appropriate venue for care. Moreover, the rule notes that the pharmacist "must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings."

The Board has published several template protocols that may serve as a useful starting point for pharmacists in fulfilling their obligations under the general requirements. Specific template protocols are provided for:

- Cold sores
- Influenza – treatment and prophylaxis
- Group A streptococcal pharyngitis
- Uncomplicated urinary tract infections
- Statins for patients with diabetes
- Short-acting beta agonists

Use of these template protocols is subject to the Pharmacist Prescriptive Authority Protocol Terms of Use. These template protocols were developed collaboratively by physicians, pharmacists, nurses, insurers, and lawyers at various protocol workshops held between November 2017 and March 2018. The Board is grateful for the efforts of the many participants who contributed constructively to their development!

New Continuation of Therapy Rule: Frequently Asked Questions

Rule 27.01.03.303.03(b) took effect on July 1, 2018, and states:

> A pharmacist may refill a prescription for a non-controlled drug one (1) time in a six (6)-month period when the prescriber is not available for authorization. In such cases, a pharmacist may dispense a refill up to the quantity on the most recent fill or a thirty (30)-day supply, whichever is less.

Board staff has received several questions on this new provision:

My patient spilled her liquid antibiotic. Can I use this rule to authorize a "refill"? The rule explicitly excludes **only** controlled substances (CS), thus there is no express prohibition on refilling liquid antibiotics.

We have a lot of tourists passing through my pharmacy on the way to the national park. Did the previous refill have to be dispensed at my store? The rule does not explicitly limit refills to the same pharmacy as the previous fill.

What if a drug product comes in a standard unit of dispensing that may exceed a 30-day supply (eg, an inhaler)? The rule explicitly excludes **only** CS, thus there is no express prohibition on refilling drug products that come in a standard unit of dispensing that may exceed a 30-day supply.

As described in the previous Board *Newsletter*, when a specific act is not explicitly prohibited, it falls to the pharmacist's professional judgment, with two questions set forth as guidance:

1. If someone asks why I made this decision, can I justify it as being consistent with good patient care and with the law?
2. Would this decision withstand a test of reasonableness (eg, would another prudent pharmacist make the same decision in this situation)?

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National Pharmacy Compliance News

September 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation.* Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when

mixed with water and sequesters excess opioids and other drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further,,USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The Standard plan is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically.

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For example, in the case of a patient having spilled a liquid antibiotic, could you justify the "refill" as being consistent with good patient care? Would your peers consider this act reasonable? If you can comfortably answer "yes" to these questions, you are generally on solid footing. As more nuanced scenarios emerge in practice, please use the questions above related to professional judgment to help navigate the "gray areas" that arise.

Updated CPE Requirements and Transition Plan

Among the updates to the Board's rules was a streamlining of continuing pharmacy education (CPE) requirements. Per Rule 27.01.02.033:

> Each pharmacist applicant for license renewal must complete fifteen (15) CPE hours each calendar year between January 1 and December 31.
>
> 1. ACPE. At least twelve (12) of the CPE hours obtained must be from programs by an ACPE provider that have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ACPE credits must be reported to and documented in CPE Monitor in order to be accepted.
> 2. CME. A maximum of three (3) of the hours may be obtained from CME, if the credits are:
>   a. Obtained from an ACCME accredited provider; and
>   b. A certificate is furnished that identifies the name of the ACCME accredited provider and a clear reference to its accreditation status, the title of the CME program, the completed hours of instruction, the date of completion, and the name of the individual obtaining the credit. All CME certificates must be submitted to the Board between December 1 and December 31.

There are several items of note in the new rule.

First, all the specific requirements from previous years were **removed.** No longer must a pharmacist complete a minimum number of live, law, immunization, or sterile compounding credits as a matter of law. That is not to say that pharmacists cannot or should not receive live, law, immunization, or sterile compounding credits; it is just not a legal mandate to do so. As self-directed, lifelong learners, pharmacists should choose the most relevant CPE programs for their professional development and maintenance of competence.

Second, a minimum of 12 hours must be obtained from Accreditation Council for Pharmacy Education (ACPE)-accredited programs, and the Board will **only** accept CPE credits reported to CPE Monitor®.

Third, a maximum of three hours may be obtained from continuing medical education (CME) and only if the course meets specific documentation requirements. No longer will attendance sheet-based documentation be accepted.

Lastly, the link between license renewal and CPE completion is severed, and 15 hours of CPE must be obtained each **calendar year** between **January 1 and December 31.** So, what does this mean for the transition year? Initially, the Board will accept 15 credits obtained between July 1, 2018, and December 31, 2019. The Board will fully transition to a calendar year audit in 2020.

Opioid Antagonists Reporting Requirement Reminder

This is a reminder to all dispensers that as of July 1, 2018, "All controlled substances, **and opioid antagonists as defined in Idaho Code, section 54-1733B . . .**" are required to be reported to the Idaho Prescription Monitoring Program. This requirement includes any dispenses of the drug naloxone.

Some pharmacies have reported problems when reporting opioid antagonist dispensations done by a pharmacist, or a prescriber who does not have a Drug Enforcement Administration (DEA) registration number. For those dispensations, please use the pharmacy's DEA number in the data field requiring the prescriber's number.

There have also been questions regarding the scheduling coding in pharmacy software systems. Please check with your software vendor to see if they have a specific code for reporting purposes of nonscheduled drugs.

If you have any further questions, please contact the Board at 208/334-2356 or pmp@bop.idaho.gov.

DEA Position on Transfer of 'On File' CS Prescriptions

Pharmacists continue to call Board staff with understandable confusion on whether and how "on file" CS prescriptions that were never filled may be transferred. The North Carolina Board of Pharmacy has provided a recap on this topic in its July 2018 *Newsletter*, which is reprinted below with permission:

> In April 2017, word began swirling that Drug Enforcement Administration (DEA) viewed transfers of "on file" CS as not allowed. On July 7, 2017, Loren Miller, associate section chief, Liaison and Policy Section, Diversion Control Division, DEA, sent an email to Carmen Catizone, executive director of the National Association of Boards of Pharmacy®, setting forth DEA's view on the matter.
>
> In that email (found [here]), Mr Miller states the view that Title 21 Code of Federal Regulations (CFR) 1306.25 allows a pharmacy, "once it has filled an original prescription for a controlled substance in Schedule III-V," to "transfer the original prescription information to another DEA registered pharmacy for the purposes of allowing that second pharmacy to then dispense any remaining valid refills . . ." Mr Miller further stated that "an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered pharmacy."

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Mr Miller then stated that, based on "the preamble" of an "interim final rule," it is DEA's "policy" that an electronic prescription for a CS of any Schedule may be "forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy" even if that prescription had not been filled.

To say that DEA's positions in this matter create a mess is a gross understatement. First, while Mr Miller's reading of Title 21 CFR 1306.25 is textually plausible, it represents a departure from decades of standard pharmacy practice, and there has been no suggestion from DEA or anyone else that the standard practice of transferring "on file" but unfilled (as opposed to once-filled) CS prescriptions has caused or materially contributed to CS abuse or misuse. Second, neither Mr Miller's email nor any language in the preamble he references contains so much as a hint as to what an appropriate mechanism for "forwarding" (and documenting the forwarding of) an unfilled electronic CS prescription would be. Third, Mr Miller's email does not explain why "forwarding" an unfilled electronic CS prescription is substantively different than transferring an unfilled CS prescription, whether electronic, verbal, or written. Fourth, DEA's position creates not only an incentive, but a practical necessity for patients seeking to change their pharmacy of choice to obtain duplicate CS prescriptions from their caregiver. Interpretations and policies that guarantee duplicate prescriptions for CS in multiple pharmacies hardly seem consistent with the Controlled Substances Act's purpose to create a controlled, closed distribution system and minimize CS abuse and misuse.

All that said, however, DEA has shown no inclination to reconsider or clarify these positions. Where does that leave us?

1. Though "forwarding" of unfilled electronic CS prescriptions is available by "policy," the lack of any guidance from DEA on how a "forwarding" should occur and be documented means that most pharmacies and pharmacists are reluctant to entertain the practice. And who can blame them?
2. For unfilled verbal prescriptions for Schedule III-V CS, DEA's position means that there is no mechanism for moving them from one pharmacy to another.
3. For unfilled paper prescriptions for Schedule III-V CS, a pharmacy could return the original to the patient to physically carry to another pharmacy. Board staff understand completely the practical problems of this approach.

Some pharmacists have inquired why Board staff, the Board, or the [legislature] have taken this position. As the above makes clear, none of the three are to blame. The present state of affairs is attributable solely and entirely to DEA. Board staff will, of course, update pharmacists if DEA sees reason and backs away from these positions. Until then, send your cards, letters, and calls to DEA.

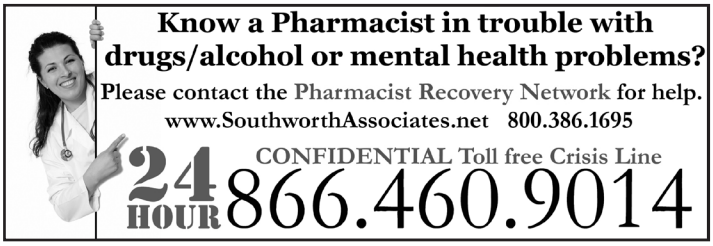
Proposed Rulemaking Session Scheduled: October 24

The Board's proposed rulemaking session is scheduled for October 24, 2018, at 1 PM MDT and will be held at the Idaho State Capitol, Room WW53, 700 W Jefferson Street, Boise, ID. The current drafts of all proposed rules will be available on the Board's website (*https://bop.idaho.gov/code_rules*).

The Board encourages all interested parties to review the proposed rules and provide feedback to the Board. Comments may be submitted in writing to the Board's executive director (alex.adams@bop.idaho.gov; or by fax to 208/334-3536) in advance of the meeting. In addition, verbal comments may be delivered in person at the meeting.

Help Is Available for Impaired Pharmacists Through Idaho PRN

The Idaho State Board of Pharmacy subsidizes the state's Pharmacist Recovery Network (PRN). The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence, including intervention, consultation, monitoring, advocacy, education, and support. If you need confidential help – or know an associate who does – please contact the program's vendor, Southworth Associates, by phone at 866/460-9014.



Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read it carefully.

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Alex J. Adams, PharmD, MPH - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager